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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jeffrey Karl Sutton

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EXAMINER

BLANCO, JAVIER G

ART UNIT

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3774

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,186	Applicant(s) SUTTON ET AL.	
	Examiner JAVIER G. BLANCO	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/16/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,9-11,13-23,28-46 and 48-109 is/are pending in the application.
- 4a) Of the above claim(s) 11,14,17,18,20-23,28-46 and 48-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 9, 10, 13, 15, 16, and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's cancellation of claims 24-27 in the reply filed on May 16, 2007 is acknowledged.
2. Applicant's amendment of claims 1, 3, 4, 9-11, 13, 15, and 19 in the reply filed on August 9, 2007 is acknowledged.
3. Applicant's cancellation of claims 2, 5-8, 12, and 47 in the reply filed on August 9, 2007 is acknowledged.
4. Applicant's amendment of claims 1, 3, 4, 9-11, 13, 15, and 19 in the reply filed on November 16, 2007 is acknowledged.

Claim Objections

5. Claim 1 is objected to because of the following informalities:
 - a. Please substitute "an inner plate comprising an inner surface having a first articulation surface, an outer surface, and a body portion therebetween" (see claim 1, lines 5-6) with --an inner plate comprising an ~~inner~~ outer surface having a first articulation surface, an ~~outer~~ inner surface, and a body portion therebetween--. Appropriate correction is required.
 - b. Please substitute "wherein the channel comprises means for capturing the screw" with --wherein the elongated channel comprises means for capturing the screw--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3, 4, 9-11, 13, 15, 16, 19, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 1, the limitation "*wherein the screw comprises a longitudinal shaft having a thread thereon*" (see claim 1 at page 3, of the most recent response, at line 10) is indefinite as to the scope of the invention. Claim 1 already recites screw 37 as "having an elongated shaft and a threadform thereon" (see claim 1 at page 3, of the most recent response, at line 7). Claims 3, 4, 9-11, 13, 15, 16, 19, and 21 depend on claim 1.

b. Regarding claim 1, the limitation "*wherein the elongated channel further comprises an anterior recess and a posterior recess defined by necks in the elongated channel*" (see claim 1 at page 3, of the most recent response, at line 13) is indefinite as to the scope of the invention. Are the "anterior recess" and "posterior recess" the "means for capturing the screw" (see claim 1 at page 3, of the most recent response, at line 9)? Compare said limitation to the limitations claimed in dependent claims 9-11. Claims 3, 4, 9-11, 13, 15, 16, 19, and 21 depend on claim 1.

c. Regarding claim 13, the limitation "*wherein the screw further comprises a head*" is indefinite as to the scope of the invention. Claim 1 already recites screw 37 as comprising proximal head
40.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 3, 4, 9-11, 13, 15, 16, 19, and 21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 12, 13, 15, 18-20, 23-26, 37, 39, 40, and 46-48 of copending Application No. 11/015,927.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a prosthetic endplate comprising an outer plate, an inner plate, and means for adjusting/moving one plate in relation to the other plate. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 3, 4, 9-11, 13, 15, 16, and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hochshuler et al. (US 6,045,579 A).

Referring to Figures 6A and 7-16, Hochshuler et al. discloses a prosthetic endplate in an intervertebral motion disc having an anterior end (22) and a posterior end (24), the endplate disc comprising:

- a. An outer plate (14) comprising an outer surface *adapted for fixation* to a first vertebral body, an inner surface (**first interpretation:** inner surface of plate 14; **second interpretation:** rib 85; **third interpretation:** inner surface of plate 14 + rib 85), and a body portion therebetween;
- b. An inner plate (12) comprising an outer surface having a first articulation surface, an inner surface (**first interpretation:** inner surface of plate 12; **second interpretation:** rib 84; **third interpretation:** inner surface of plate 12 + rib 84), and a body portion therebetween; and
- c. Means for selectively adjusting a relative position of the inner plate upon the outer plate, wherein the means for selectively adjusting a relative position is disposed upon the inner surfaces and comprises:
 - i. An elongated channel (**first interpretation:** Figures 10-15, longitudinal channel created in between ribs 84 and extending from anterior end 22 to posterior end 24; **second interpretation:** slots 60; slot 90 and/or slot 92; slots 100, 104 and/or slots 102, 106; **third**

interpretation: Figures 11-15, channel extending from one rib 85 to the opposite rib 85, or through-hole on each of ribs 85 and extending from one rib 85 to the opposite rib 85), and

ii. An elongated projection (**first interpretation:** Figures 10-15, ribs 85 + receiving sections 87; **second interpretation:** struts 30, which run in the anterior-posterior direction; pin 86 and/or pin 88; pin 86 and/or pin 88; **third interpretation:** Figures 12-15, receiving sections 87) *adapted to mate* (directly or indirectly) with the elongated channel, wherein the elongated projection comprises a threaded throughhole (**first interpretation:** threaded bore of receiving sections 87, which will receive screw 80; **second interpretation:** bore receiving pin 70; pin 86 and/or pin 88; pin 86 and/or pin 88; **third interpretation:** threaded bores of receiving sections 87, which will receive pins 86, 88) running in the direction of the elongation, and

iii. A captured screw (**first interpretation:** threaded screw 80; **second interpretation:** threaded pins 86, 88) disposed within the throughhole, the screw having an elongated shaft and a threadform thereon, the threadform being complimentary to the threaded throughhole.

Wherein the screw further comprises a blunt distal tip (Figures 10 and 12-15), and a proximal head (Figures 10-15) having a slot (Figure 11), the elongated shaft comprising a recess (Figures 10 and 12-15) *adapted for reception* of a locking clip (i.e., locking clip is not positively claimed, therefore the elongated shaft is capable of receiving a locking clip if one skilled in the art so desires), as shown in Figures 14 and 15 (e.g., locking ring/clip 98). The elongated channel further comprises an anterior recess (e.g., an anterior recess/opening, as shown in Figures 10 and 12-15) and a posterior recess (e.g., a posterior recess/opening, as shown in Figures 10 and 12-15) defined by necks (e.g., “necks” created by receiving sections 87, **or** “necks” created by ribs 84) in the elongated channel, wherein the blunt distal tip and the proximal head of the screw are

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respectively seated in the anterior recess and the posterior recess (see Figures 10-15). Said elongated channel/recess is formed upon the inner surface of the inner plate and said projection is formed upon the inner surface of the outer plate. Alternatively (as shown in the Figures), said elongated channel/recess is formed upon the inner surface of the outer plate and said projection is formed upon the inner surface of the inner plate (i.e., reversal of parts). The “locking means for locking the screw” (see claims 15 and 16) is the cam of cam pins 86, 88.

12. Claims 1, 3, 4, 9, 10, 13, 15, 16, and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cohen et al. (US 6,454,806 B1).

Referring to Figures 14A-14C and 15A-15C, Cohen et al. disclose a method of adjusting a position of a prosthetic endplate, comprising the steps of:

- a)** Providing a prosthetic endplate having an anterior end and a posterior end, the endplate comprising **(i)** an outer plate (Figures 14A-14C: plate 91; Figures 15A-15C: plate 110) comprising an outer surface, an inner surface, and a body portion therebetween, and **(ii)** an inner plate (Figures 14A-14C: plate 91; Figures 15A-15C: plate 110) comprising an outer surface, an inner surface, and a body portion therebetween,
- b)** Fixing the outer surface of the outer plate to a first vertebral body to produce a first relative position of the inner plate upon the outer plate, and
- c)** Selectively adjusting (i.e., “means for selectively adjusting”) the first relative position to a second relative position of the inner plate upon the outer plate.

The inner surfaces comprise an elongated channel/recess (Figures 14A-14C: groove 94 and/or inner channel 95; Figures 15A-15C: grooves 115) and an elongated projection (Figures

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14A-14C: wedges 92; Figures 15A-15C: guides 114) *adapted to mate* with said elongated channel/recess, wherein the elongated projection runs in the anterior-posterior direction. Said elongated channel/recess is formed upon the inner surface of the inner plate and said projection is formed upon the inner surface of the outer plate. Alternatively (as shown in the Figures), said elongated channel/recess is formed upon the inner surface of the outer plate and said projection is formed upon the inner surface of the inner plate (i.e., reversal of parts). The elongated projection comprises a through-hole (e.g., bore) running in the direction of the elongation (see Figures 14A-14C), wherein the through-hole (e.g., bore) is threaded (see Figures 14A-14C; see column 10, lines 28-41) which thread is complementary to the thread of a screw (screw 93) being disposed within the through-hole (e.g., bore). The channel/recess comprises means for capturing the screw such as a shoulder or neck (e.g., counterbore). Cohen et al. disclose “locking means for locking the screw” (see claims 15 and 16) as cam 112 (see Figures 15A-15C). The elongated shaft of the screw comprising a recess (see Figures 14A-14C) *adapted for reception* of a locking clip (i.e., locking clip is not positively claimed, therefore the elongated shaft is capable of receiving a locking clip if one skilled in the art so desires).

Response to Arguments

13. With regards to the 102(b) rejection based on Hochshuler et al. (US 6,045,579 A), Applicants’ arguments filed November 16, 2007 have been fully considered but they are not persuasive.

a. The Applicants argue that Hochshuler et al. ‘579 do not disclose the blunt distal tip and proximal head of the screw as “*respectively seated in the anterior recess and the posterior*

recess” of the elongated channel. The Examiner respectfully disagrees. Applicants’ arguments have been adequately addressed in the 102(b) rejection (above).

14. With regards to the 102(b) rejection based on Cohen et al. (US 6,454,806 B1), Applicants’ arguments filed November 16, 2007 have been fully considered but they are not persuasive.

a. The Applicants assert “*Claim 1 has been amended to contain all the requirements of claim 12. Since claim 12 was not rejected in view of Cohen, this rejection should be withdrawn.*” The Examiner respectfully disagrees.

It is noted that now-cancelled claim 12 (“wherein the means comprises a recess in the elongated shaft of the screw, the recess being *adapted for reception* of a locking clip) depended on now-cancelled claim 8 (“wherein the channel comprises means for capturing the screw”). Therefore claim 1, as currently amended, do not have all of the requirements of now-cancelled claim 12 (i.e., does not specify the “means for capturing the screw”, previously claimed in claim 8, as comprising “a recess in the elongated shaft of the screw, the recess being *adapted for reception* of a locking clip”). Claim 1, as currently amended, recites the screw as having an elongated shaft “comprising a recess *adapted for reception* of a locking clip”. As clearly seen in Figures 14A-14C, the elongated shaft of the screw comprises several recesses, any of which is *adapted for reception* of a locking clip (i.e., locking clip is not positively claimed, therefore the elongated shaft is capable of receiving a locking clip if one skilled in the art so desires).

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/Dave Willse/

Primary Examiner, Art Unit 3738